



PTO/SB/08a/v (07-05)

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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 4 Attorney Docket Number 01946/100G906-US2

Complete if Known

Application Number	10/615,213-Conf. #8060
Filing Date	July 7, 2003
First Named Inventor	William E. Bay
Art Unit	1625
Examiner Name	R. J. Desai

U.S. PATENT DOCUMENTS					
Examiner Initials ¹	Cite No. ¹	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)	MM-DD-YYYY		
KD	AA	3,795,739	3/5/74	Birkmayer et al.	
KD	AB	3,939,253	2/17/76	Bodor et al.	
PM	AC	4,035,507	7/12/77	Bodor et al	
PM	AD	4,061,466	12/6/77	Sjoholm et al.	
PM	AE	4,147,767	4/3/79	Yapel	
KD	AF	4,207,341	6/10/80	Mandfred et al.	
KD	AG	4,221,815	9/9/80	Weyer et al.	
KD	AH	4,238,506	12/9/80	Stach, deceased et al.	
KD	AI	4,239,754	12/16/80	Sache et al.	
KD	AJ	4,393,192	7/12/83	Curatolo et al.	
P	AK	4,442,090	4/10/84	Kakeya et al.	
P	AL	4,499,299	2/12/85	Bernstein et al.	
P	AM	4,462,991	7/31/84	Higuchi et al.	
P	AN	4,656,161	4/7/87	Herr et al.	
P	AO	4,654,327	3/31/87	Teng	
P	AP	4,692,433	8/8/87	Hostetler et al.	
P	AQ	4,757,066	7/12/88	Shiokari et al.	
P	AR	4,835,312	5/30/89	Itoh et al.	
KD	AS	4,873,087	10/10/89	Morishita et al.	
P	AT	4,878,942	11/7/89	Motegi et al.	
KD	AU	4,900,730	2/13/90	Miyauchi	
P	AV	4,927,928	5/22/90	Shroot et al.	
P	AW	5,066,487	11/19/91	Morelle et al.	
KD	AX	5,352,461	10/4/94	Feldstein et al.	
P	AY	5,665,700	9/9/97	Cho et al.	
P	AZ	5,705,529	1/6/98	Matyus et al.	
P	BA	5,447,728	9/5/95	Milstein et al.	
P	BB	5,451,410	9/19/95	Milstein et al.	
P	BC	5,541,155	7/30/96	Leone-Bay et al.	
P	BD	5,629,020	5/13/97	Leone-Bay et al.	
P	BE	5,643,957	7/1/97	Leone-Bay et al.	
P	BF	5,650,386	7/22/97	Leone-Bay et al.	
P	BG	5,709,861	1/20/98	Santiago et al.	
P	BH	5,714,167	2/3/98	Milstein et al.	
P	BI	5,750,147	5/12/98	Kantor et al.	
P	BJ	5,766,633	6/16/98	Milstein et al.	
P	BK	5,773,647	6/30/98	Leone-Bay et al.	
P	BL	5,776,888	7/07/98	Leone-Bay et al.	
P	BM	RE35862	7/28/98	Steiner et al.	
P	BN	5,792,451	8/11/98	Sarubbi et al.	
P	BO	5,804,688	9/8/98	Leone-Bay et al.	

Examiner Signature	R. Desai	Date Considered	3/9/06
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				Attorney Docket Number	01946/100G906-US2

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		Number-Kind Code ² (if known)			
RD	BP	5,811,127	9/22/98	Milstein et al.	
RD	BQ	5,863,944	1/26/99	Leone-Bay et al.	
RD	BR	5,866,536	2/2/99	Leone-Bay et al.	
RP	BS	5,876,710	3/2/99	Leone-Bay et al.	
RD	BT	5,879,681	3/9/99	Leone-Bay et al.	
RP	BU	5,939,381	8/17/99	Leone-Bay et al.	
RD	BV	5,958,457	9/28/99	Santiago et al.	
RD	BW	5,965,121	10/12/99	Leone-Bay et al.	
RP	BX	5,989,539	11/23/99	Leone-Bay et al.	
RD	BY	5,990,166	11/23/99	Leone-Bay et al.	
RD	BZ	6,001,347	12/14/99	Leone-Bay et al.	
RD	CA	6,051,258	4/18/00	Kantor	
RP	CB	6,051,561	4/18/00	Leone-Bay et al.	
RD	CC	6,060,513	5/9/00	Leone-Bay et al.	
RD	CD	6,071,510	6/6/00	Leone-Bay et al.	
RD	CE	6,071,538	6/6/00	Milstein et al.	
RD	CF	6,090,958	7/18/00	Leone-Ba et al.	
RD	CG	6,099,856	8/8/00	Milstein et al.	
RD	CH	6,221,367	4/24/01	Milstein et al.	
RD	CI	6,242,495	6/5/01	Leone-Bay et al.	
RD	CJ	6,245,359	6/12/01	Milstein et al.	
RD	CK	6,313,088	11/6/01	Leone-Bay et al.	
RD	CL	6,344,213	2/5/02	Leone-Bay et al.	
RD	CM	6,346,242	2/12/02	Leone-Bay et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
AK		EP-0036145	9/23/81		
RI		GB-2095994	10/13/82		
RD		EP-226223	6/27/87		
RP		EP-0365183	10/6/89		
RD		WO-8807378	10/6/98		
RD		EP-0576941	6/19/93		
RD		JP-2239980	9/21/90		
RD		EP-0517211	9/12/92		
RD		WO-9747470	12/18/97		
RD		WO-0007979	5/18/00		
RD		WO-0006534	2/10/00		
RD		WO-0006184	2/10/00		

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
RO		WO-0048589	8/24/00			
RO		WO-0009390	10/12/00			
RO		ES-369853	7/16/71			
RO		WO-9929685	6/17/99			
RO		EP-0225189	10/6/87			

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
RO		Picciola G.: "Sintesi Di Acidi Chiazzoliniici E. Benzossazinonici E Studio Delle Loro Proprietà Antinflammatorie" IT, Società Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation	
RO		Chem Abs 73548-12-6 (4/1991)	
RO		Chem Abs 70204-54-5 (4/1991)	
RO		Chem Abs 184360-83-342 (1975) "Solubility and disassociation constants of some alicyclic acids"	
RO		Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)	
RO		Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1979)	
RO		Leone-Bay, A. et al., "The evolution of an oral heparin dosing solution" Drugs of the Future vol 22 (8) 885-891 (1997)	
RO		Brayden, D. et al. "Heparin Absorption across the intestine; Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations and in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)	
RO		Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
RO		Leone-Bay, A. "4-[4-(2-Hydroxybenzyl) amino]phenyl]-butyric Acids as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no. 13 pp 2571-2578 (1996)	
RO		Leone-Bay, A. "N-Acytated alpha-amino acids as novel oral delivery agents for proteins"; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)	
RO		Leone-Bay, A. "N-Acytated alpha-amino acids as novel oral delivery agents for proteins"; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)	

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Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
RD		Ho Koc-Kan; et al. "A Practical Synthesis of ω -aminoalkanoic acid derivatives from Cycloalkanones" Synthetic Communication, vol. 26, no. 14:2641-2649 (1996)	
RD		Gurrier and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochimica Acta, 7 (1973) 231-239	
RD		Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1998)	
RD		Brown et al., J. Med. Chem. 27:79-81 (1984)	
RD		Johansen, Marianne, et al. "The Kinetics of decompr. Of various N-Mannichi bases of salicylamide" Int. J. Pharm. 1980, 7(2): 119-27 (1980)	
RD		August 1, 2000 International Search Report issued in connection with PCT Application No. PCT/US00/09390	
RD		Baughman, R. et al., Circulation (1998), 98 (16) 1610-1615.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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